Improving Audit Effectiveness

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Experience Levels

• Do you have any **auditing experience**? Rate yourself on a scale of 1 to 5.
  – 1 being little or no experience
  – 5 being a very experienced certified auditor

• How many are responsible for their internal audit system or auditing outside suppliers?
Learning Session Objective

• Provide you with information on the overall audit process that could assist you in performing audits that:
  – Ensure processes are working effectively and efficiently
  – Assist the audited process or organization to improve
  – Provide Value to your Management Team
Agenda

– What is a Quality Audit?
– Auditor Characteristics, Skills and Responsibilities
– Audit Categories and Audit Types
– The Auditing Process - Overview
  • Audit Preparation
  • Audit Execution
  • Audit Administration & Closure
  • Action Implementation & Effectiveness Verification
– Questions and Answers
– Learning Session Evaluation
What is a quality audit?

Multiple Choice Question

A. A chance to find someone doing something wrong
B. A reason to have to do more work
C. A method to determine how effective processes are at providing quality goods and services
D. A good way to get out of doing my regular job
What is a quality audit?

Multiple Choice Question – Best answer

A. A chance to find someone doing something wrong
B. A reason to have to do more work
C. A method to determine how effective processes are at providing quality goods and services
D. A good way to get out of doing my regular job
Terms related to Audits…  (Ref. ISO9000-2015)

• **Audit** - Systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

• Remember it is only a “Sample” of the system.
Terms related to Audits… (Ref. ISO9000-2015)

• **Objective evidence** – data supporting the existence or verity of something.
  
  – Note 1: Objective evidence can be obtained through observation, measurement, test, or other means.

  – Note 2: Objective evidence for the purpose of audit generally consists of records, statements of fact or other information which are relevant to the audit criteria and verifiable.

  – Verity = Truth, fact, reality
Terms related to Audits... (Ref. ISO9000-2015)

- **Audit criteria** – set of policies, procedures or requirements used as a reference against which objective evidence is compared.

- **Audit evidence** – records, statements of fact or other information, which are relevant to the audit criteria

- **Audit findings** – Results of the evaluation of the collected audit evidence against audit criteria
Why do we conduct audits?

Multiple Choice Question:
A. Because ISO says so
B. To improve the effectiveness of the Quality Management System (QMS)
C. To give the quality people something to do
D. They are a management tool to determine how effectively we implement processes and procedures that affect quality
Why conduct audits?

Multiple Choice Question:

A. Because ISO says so

B. To improve the effectiveness of the Quality Management System

C. To give the quality people something to do

D. They are a management tool to determine how effectively we implement processes and procedures that affect quality
Characteristics of an Effective Auditor

- Ethical / Honest
- Open-minded
- Diplomatic
- Observant / Perceptive
- Versatile / Adaptive
- Tenacious
- Objective
- Organized
- Prompt (On-Time)
- Self-Managing / Reliant
- Friendly
- Professional
Skills of an Auditor

• Ability to make others feel comfortable
• Good Oral communication at all levels of an organization
• Effective Listening
• Project Management
• Time management
• Organized
• Able to adapt to the differing personalities of others
• Effective Writing
What Auditors Need To Know…

• Should have a general knowledge about:
  – Processes – Inputs/Outputs
  – Audit principles, procedures, and techniques
  – Business system processes and related documentation
  – The area being audited
  – Understanding that they are the eyes and ears of management regarding the area being audited
Auditor Roles & Responsibilities

Lead Auditor – Responsible for Audit Success

- Defines Team Member Assignments
- Creates & Distributes Audit Plan
- Coordinates audit logistics
- Conducts opening and closing meetings
- Ensures audit team members perform assignments
- Prevents and resolves conflicts
- Advises auditee/client, if audit objectives cannot be met
- Prepares and completes the audit report
- Collects working documentation and objective evidence
- Ensures follow-up to Corrections and Findings
Auditor Roles & Responsibilities

Audit Team Member

- Commit the necessary time to do the audit effectively
- Prepares for their assignment
  - Obtains process documentation from auditee
  - Prepares working documentation
- Complete the audit as scheduled
- Perform audits in a professional manner
- Collects and analyzes information and evidence through interviews and verification
- Documents findings, corrections, opportunities for improvement
- Contributes to the audit report
Method to Recruit Internal Auditors

You can always use good auditors on your team

1\textsuperscript{st} - Talk with Human Resources –
• Explain how being an auditor helps develop interpersonal, communication, writing skills and effective listening.
• Explain how auditing helps the individuals learn the people and processes in the organization. Provide examples
• It is a good way to develop leadership skills

2\textsuperscript{nd} – Target the individuals you believe have the skills needed
• Talk to them and gauge their interest. Ask them to express their interest to their boss. It would help them learn processes to be more effective at their job.

3\textsuperscript{rd} - Have HR send an announcement to the organizations leadership team requesting an individual from each function.

4\textsuperscript{th} – Start training them, have them shadow you on an audit, have them attend an audit class and convince them to work toward certification.
Audit Categories (Internal and External)

- **First Party Audit**
  - Internal Audits (Performed by internal employees)

- **Second Party Audit** – Contract exists/pending
  - Supplier Audits by your organization
  - Customer Audit of Organization

- **Third Party Audit** – Compliance to Standards
  - DNV, TUV, BV, CSA, Regulatory Audit
Types of Audits

Most common audits performed

- Product Audit
- Systems Audit
- Process Audit
Types of Audits

• **Process Audit**

Audits performed to verify that a specific identified process or procedure is being performed as defined and the outcomes meet the requirements.
Process Audits....

- Verify inputs, actions, and outputs are in accordance with defined requirements.
- Examine the adequacy and effectiveness of the process.
- Identify Opportunities for Improvement.
What is a Process?

STEP ONE
INPUTS
OUTPUT
START
INPUTS
INPUTS
OUTPUT

STEP TWO
INPUTS
INPUTS
OUTPUT
OUTPUT
INPUT

STEP THREE
INPUTS
INPUTS
OUTPUT
OUTPUT
INPUT

STEP FOUR
INPUTS
INPUTS
OUTPUT
OUTPUT
INPUT

OUTPUT
What is a Process?

PROCESS A
STEP ONE
START
MATERIALS
LABOR
METHODS
MACHINES / EQUIPMENT / TOOLS
ENVIRONMENT
INPUTS
OUTPUT
WIDGET
WIP
IN-PROCESS INSPECTION RECORD
FINAL INSPECTION RECORD
INPUT
FILE ROOM

PROCESS A
STEP TWO
INPUT
OUTPUT
WIDGET
WIP

PROCESS A
STEP THREE
INPUT
OUTPUT
WIDGET
WIP

PROCESS A
STEP FOUR
INPUT
OUTPUT
WIDGET
FINISHED GOOD

PROCESS B
INPUT
OUTPUT

START
IN-PROCESS INSPECTION RECORD
FINAL INSPECTION RECORD
FILE ROOM
Example of a Process

FRYING AN EGG FOR BREAKFAST

START
Turn on stove burner on medium heat.
Electricity / Stove
INPUT

Place frying pan on stove burner.
Frying Pan
INPUT

Add two tablespoons of vegetable cooking oil to frying pan.
Vegetable Cooking Oil
INPUT

Break shell and add 1 egg into frying pan.
Egg
INPUT

Cook egg for 2 minutes.

Sunny Side Up?
No
Turn egg with spatula. Cook for 2 more minutes.
Spatula
INPUT

Yes

Use spatula to remove egg from frying pan.
Spatula
INPUT

Turn off Stove.

STOP

Use fork to eat the egg. Add salt / pepper as needed.
Fork / Salt / Pepper
INPUT

Set plate on table and allow to cool for 1 minute.
Table
INPUT

Place egg onto plate.
Plate
INPUT

Use spatula to remove egg from frying pan.

OUTPUT

A Yummy Breakfast!
A Process Audit...

Multiple Choice Question:
A. Verifies that people are performing what the documentation says
B. Verifies specific requirements are being met
C. Evaluates to what extent the process is effective
D. Looks beyond just compliance
E. All of the above
A Process Audit…

Multiple Choice Question:

A. Verifies that people are performing what the documentation says
B. Verifies specific requirements are being met
C. Evaluates to what extent the process is effective
D. Looks beyond just compliance
E. All of the above
Objective of an Audit

To provide **feedback** that **management** perceives as **value-added** regarding the effectiveness of their processes in meeting their customers’ requirements.
Audit Process

Always remember….

The Auditee is one of your customers. They expect a quality product just like you do.

The customer should find the audits valuable to their organization.
Overview of Auditing Process

Audit Planning, Preparation, & Notification → Audit Execution → Audit Administration & Closure → Action Implementation & Effectiveness Verification
Audit Planning, Preparation & Notification

Audit Planning, Preparation, & Notification

Prepare Audit Plan and Notify Auditee.

Make travel / logistics arrangements.

Review process documentation.

Review results of previous audits.


Audit Execution

Audit Administration & Closure

Action Implementation & Effectiveness Verification

Review process documentation.

Review results of previous audits.
Audit Planning, Preparation & Notification

**AUDIT PLAN**

Audit Number:
Quality System Number/Element Name:

**Audit Objective(s):**
Planned Audit Start Date:
Lead Auditor Assigned:
Location/Function/Departments to be audited:

Audit Team:

**Completed by QA**
List dates that each item was completed

Information from previous audits:
ISO Element Reviewed
QA Manual Reviewed
List Procedure Names/Numbers Reviewed:

Audit Plan

Checklist completed and attached:

Quality Assurance

Date
Audit Planning – Initiating the Plan

AUDIT PLAN

Audit Number:
Quality System Number/Element Name:
**Audit Objective(s):**
Planned Audit Start Date:
Lead Auditor Assigned:
Location/Function/Departments to be audited:

__________________________________________

__________________________________________

Audit Team Members:
Auditee Notified – (Name, Title, Date, Email, Phone)
Audit Planning, Preparation & Notification

- Prepare Audit Plan and Notify Auditee
- Make travel / logistics arrangements
- Review process documentation
- Review results of previous audits
- Prepare Working Documentation. Conduct Document Review

Phone and Email Notification
Audit Planning, Preparation & Notification

Develop a Checklist

- Rental Car
- Hotel Room
- Airline Ticket
- Work Permit [International]
- Passport [International]
- Working Room
- Room for Opening / Closing Meetings
- Guides
- Access to Printers
- Ability to Present – room reserved
- Lunch – on site

Audit Planning, Preparation, & Notification

Prepare Audit Plan and Notify Auditee.

Make travel / logistics arrangements.

Review process documentation.

Review results of previous audits.

Audit Plan - continued

List dates that each item was completed.

- Information from previous audits: ________________________________________
- ISO Element/Standard Reviewed: ________________________________________
- QA Manual Reviewed (Policies): ________________________________________
- List Procedure Names/Numbers Reviewed/Date Completed:
  - Procedure: ________________________________________________________
  - Procedure: ________________________________________________________
  - Procedure: ________________________________________________________
  - Procedure: ________________________________________________________
- Process Map Reviewed: ________________________________________________
- Checklist completed and attached: ______________________________________
Audit Planning, Preparation & Notification

- Prepare Audit Plan and Notify Auditee.
- Prepare Working Documentation.
- Conduct Document Review.
- Make travel/logistics arrangements.
- Review process documentation.
- Review results of previous audits.

- Meets upper level system requirements
  - Look for **Gaps or Conflicts** between upper and lower level documentation
- Properly **controlled**
  - Up-To-Date
  - Revision Controlled
  - **Approved** for Use
- Identify opportunities for improvements
- Use review to help develop working documentation- Checklists
Audit Planning, Preparation & Notification

- Review previous actions taken for continued implementation and effectiveness.
- Look for similar issues in other areas / departments of the facility.
- Add additional check points to working documentation as necessary.
Audit Planning, Preparation & Notification

- Prepare Audit Plan and Notify Auditee.
- Make travel / logistics arrangements.
- Review process documentation.
- Review results of previous audits.

Working Documentation

- Create Audit Checklist
- Use existing documentation as checklist input
- Create SIPOC or Turtle Diagrams
Audit Planning, Preparation & Notification
Understanding the Process

Turtle Diagram

WHAT
Answer: The process is done with what?
   Equipment, Tools, Materials, etc.? 

WHO
Answer: The process is done with whom?
   People involved in process
   Interactions with parties involved
   Sequence with the involved process

INPUT
Answer:
   What are the inputs?
   From whom are they received?
   What are the customer wants?

PROCESS
Answer:
   Process Name
   Process Activities

OUTPUT
Answer:
   What are the outputs?
   To whom are they provided?

HOW
Answer:
   How does the process get done?
   What are the support processes?
   Who helps? And How / Procedures, Work Instructions, etc?

MEASURE
Answer:
   How is the process measured?
   With what key criteria?
   Assessments
   Measurements
Turtle Diagram-Manufacturing Example-Painting

**WHAT**
- Paint booth
- Conveyor system
- Panel hooks
- Panel Rack

**WHO**
- Associate who hangs
- Associate who reviews first piece
- Associate who changes paint color

**PROCESS**
- **Paint Panels**
  - Review work list
  - Select correct panels
  - Verify Color
  - Hang first panel
  - Conduct 1st piece inspection
  - Hang appropriate quantity of panels
  - Load into panel rack
  - Complete move ticket

**INPUT**
- Work list
- Panels
- Paint Color
- Customer wants:
  - Right color
  - Good aesthetic finish
  - Available when needed

**OUTPUT**
- Right number of panels with quality paint color as needed
- Safely stored in rack

**HOW**
- Work instructions
- Paint booth equipment manual

**MEASURE**
- On-time to mfg service
- 5s +1 audit results
- Scrap
- Thruput
Turtle Diagram - Office Example - Expense Report

**WHAT**
- Personal Computer Expense Report Form

**WHO**
- Associate
- Associate’s Supervisor / Manager

**PROCESS**
- **Expense Report Submission**
  - Complete form
  - Attach receipts
  - Sign expense report
  - Get approval signature
  - Forward to accounting for processing

**INPUT**
- Purchase or expense Receipt
  - Customer wants:
    - Accurate information
    - Correctly completed form
    - Purchases are acceptable per policy
    - Repayment of expenses to Associate

**OUTPUT**
- Approved expense report submitted to Accounting
  - Accurate information
  - Proper support documentation / receipts

**HOW**
- Knowledge / training on how to complete form – primarily shared by someone else in a department
- Knowledge of where to locate expense for (e.g., accounting forms)
- Travel Policy as reference tool

**MEASURE**
- Is it approved?
- 2% are return for changes / additional documentation
Tips for preparing to audit a Process

• Understand the process
  – Review the process map or process documentation
  – What is the process?
  – Who does the process?
  – Where is the process done?
  – When is the process done?
  – Why is the process done?
  – How is the process done? (5W, 1H)
  – How is the process’ effectiveness measured?
  – How is the process currently performing?
Audit Checklists…

• Provides structure – Auditor’s guide to an effective audit interview
• Assure requirements are covered
• Place to record data
• Helps in time management
• Can be “standardized” or “customized”
• Can include interview questions, facts / data to gather
Tips for Creating Audit Checklists

- Identify process / product name that is being audited.
- Ask multiple open-ended questions for each checklist item.
- Include process / product measures, if known.
- Identify records, forms, etc. used during the process, including name, number, revision level, revision date, retention times, and storage location.
- List other department level documents that also apply, including their document numbers, revision levels and dates.
- Include ample space for taking notes.
- Write legibly. Future audits may use your checklist during audit preparation.
- Use the checklist only as a guide. Be flexible enough to follow the audit trail.
## Audit Checklist - Example

<table>
<thead>
<tr>
<th>Requirement / Question</th>
<th>Auditee</th>
<th>Department</th>
<th>Evidence</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Requirement:</strong> If there is a drawing change during the course of the order, it is the responsibility of the Planner to revise the Traveler, and insert the revised drawing in the traveler package. <strong>Question:</strong> What happens if there is a drawing change after a traveler is issued?</td>
<td>Individual being asked the questions</td>
<td>Dept. Name</td>
<td>This section can be used to list the responses and also to show how many items were sampled and the results. <strong>Example:</strong> Five travelers were reviewed and 2 had drawing changes. Both had the correct drawings inserted in the package.</td>
<td>IC</td>
</tr>
</tbody>
</table>

1. 
2. 
3.
Audit Execution - Getting It Done

- Conduct Opening Meeting.
- Conduct interviews and observations. Collect objective evidence.
- Update Auditee periodically on issues found.
- Prepare draft audit report and determine recommended action levels.
- Review draft audit report with Auditee and assign responsibility.
- Conduct Closing Meeting.
- Audit Planning, Preparation, & Notification
- Audit Execution
- Audit Administration & Closure
- Action Implementation & Effectiveness Verification
Audit Execution – Getting It Done

**Opening Meeting**

- Circulate Attendance Sheet
- Use the Audit Plan as your meeting outline
- Introduce audit team / roles
- Explain audit purpose / scope
- Briefly review agenda (schedule)
- Provide opportunity for auditee to ask questions
- Confirm Resources / Working Room
- Safety Requirements / Equipment
- Maximum of 30 minutes

**Audit Execution**

- Conduct opening meeting.
- Conduct interviews and observations. Collect objective evidence.
- Update Auditee periodically on issues found.
- Prepare draft audit report and determine recommended action levels.
- Review draft audit report with Auditee and assign responsibility.
- Conduct closing meeting.
Auditing Techniques

• **Forward Tracing**
  – Start at beginning of process and work forward through the process

• **Backward Tracing**
  – Start at the final output of the process and work back to the beginning of the process

• **Interviewing (Individual / Group)**
  – Posing a set of open ended questions to a group or individual

• **Observing**
  – Watching someone perform a process / process step and comparing to the defined practice
Audit Execution – Getting It Done

Conduct Interviews effectively
- Introduce yourself
- Put the auditee at ease
- Practice good listening skills
- Use proper questioning techniques
- Interview the right people
- Interview all shifts / all areas when possible (good sampling coverage)

Conduct Opening Meeting.
Conduct interviews and observations. Collect objective evidence.
Update Auditee periodically on issues found.
Prepare draft audit report and determine recommended action levels.
Review draft audit report with Auditee and assign responsibility.
Conduct Closing Meeting.
Introduce Yourself

• Introduce yourself by name
• Be pleasant and professional. Do not talk down to them.
• Ask if they have been informed about the audit
• Explain the audit objective and process
  – A review of the management system, not a judgment on how well they are doing
• Explain you will be writing notes during the audit
• Ask if there are any questions
• Thank him or her for their participation and cooperation
The Human Element

- Different personalities
- Auditee would rather be somewhere else
- Auditee may be nervous, stressed, worried, etc., so be sensitive to their needs
- Auditee’s body language
- People’s perception is their reality
Questioning Techniques

- Understand the interviewee’s roles and responsibilities
- Use checklist questions as lead-in questions
- Follow the information flow (audit trail) until the objective evidence of conformity or nonconformity is found
- Ask questions in a conversational style (open ended or show me, walk me through it)
  - Auditor may have to ask questions many different ways to get to the evidence needed – Repeat the last several words, then wait.
- Use paraphrasing to ensure you have an accurate understanding
- Keep asking questions until there is an understanding of the activity with supporting objective evidence
- Be aware of the activities and details that stand out for further investigation
- Respond to answers in a neutral manner
Tips for conducting interviews

• Interview individuals from **appropriate levels and functions** performing activities or tasks within the scope of the audit

• Conduct the audit:
  – During **normal working hours** and, if possible,
  – At the normal **workplace** of the individual being interviewed

• Avoid leading or closed-ended questions
## Closed vs. Open-ended Questions

### Examples

<table>
<thead>
<tr>
<th>Closed Questions</th>
<th>Open Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Do you have a quality manual?</td>
<td>• What type of documentation do you have?</td>
</tr>
<tr>
<td>• Have you been trained to do your job?</td>
<td>• Tell me how you learned to do your particular job?</td>
</tr>
<tr>
<td>• You’re the supervisor of the machine shop, right?</td>
<td>• Tell me about your position here at ABC Company</td>
</tr>
<tr>
<td>• If a part is defective, you don’t use it, do you?</td>
<td>• What happens when you find a part that doesn’t fit or is defective?</td>
</tr>
</tbody>
</table>

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*Quality Leadership LLC*

*Improve Now for the Future*
# Leading vs. Objective Questions

## Examples

### Leading Questions

- After you’ve received a part that needs to be reworked and you’ve sent it back to the QA department, what happens next?
- Tell me about your department’s monthly quality policy meetings.
- During your six month review of contractual services with customers, what do you typically find?
- Do you put your inspection stamp on their card when you finish inspecting the job?

### Objective Questions

- If you receive a part that needs to be reworked what happens next?
- How often do you have quality meetings and what is typically covered?
- Can you tell me how often you review service contracts with customers and what you typically find?
- Tell me how you use this inspection stamp.
Leading and Closed Ended vs Objective Questions

• **Exercise:**
  
  – **Instructions:** Read the question assigned completely- It is a leading / closed-ended question.
  
  – Rewrite the question so it is not closed-ended or does not lead the auditee. The question should be open-ended (Not Yes / No) reply from auditee).
  
  – Share your answers with others at your table
  
  – Time limit: 5 minutes
Evaluating Non-Documented Activities

• Ask several Associates.
  – Are the answers consistent?

• Ask the supervisor.
  – Is there a credible message as to how the Associates know what to do?
  – Is there consistency between the supervisor’s view and the Associates’ actions?

• Look for competent work.
  – Is there evidence that process outputs meet requirements?

• Look at process and product metrics.
  – Are they consistent with expectations?

• Look for alignment of work being performed with objectives, quality policy, and organizational strategy, as appropriate.
Audit Note Taking

- Write neatly!
- Record Associate Numbers, Record Numbers, Badge Numbers, etc., to show audit trail
- Take copies of documentation, if possible.
- Notes are used to create the audit report.
- Notes are kept on file as part of the audit record.
- Your notes may be reviewed by other auditors performing future audits.
Findings, Corrections, and Opportunities for Improvement (OFI’s)

• **Findings:**
  – **Major / Minor Nonconformity:** A noncompliance, based on objective evidence, which identifies a failure to meet the requirements of the Quality Management System.
  – **Corrections:** A minor noncompliance that requires action to eliminate the detected nonconformity.
    • Example: 1 document out of 20 with a missing rev. date.
  – **Opportunities for Improvement:** OFI’S
    • Potential problems with quality management systems (also sometimes called Opportunities, Concerns, etc.)
      – Identification of areas that have a potential for a breakdown or weakness in the system.
      – Positive Feedback - Things done well or improvements since last audit
Include Positive Feedback

• Best Practices
  – Helps identify areas that can be benchmarked by others in the organization

• Significant Improvements compared to previous audits / visits

• Giving extra effort (going above and beyond)

• Positive Example: The employees in the Storeroom were very knowledgeable about their process and explained it well.
Documenting a Finding

• The finding should be stated so that it explains itself and can be resolved without further auditor inputs.

• Quote the specific requirement from the standard and/or procedure that is not be followed.
  – Include the document name, document number, and section number.
  – For example;
    “Section 6.2.1 of the Internal Quality Audits Process [List Procedure #] states that….”
Documenting a Finding

• State what has been found (pertinent information; location, product name, document, form, quantity, # sampled, # found, etc.)
  – Identify in detail the audit evidence that supports the finding
  – For example;

  “At station # 1 of the Pump Assembly Line 2 bottles of spray adhesive (Part # XYZ) were in use by the first shift operator (Assoc. #), but did not have the required age-sensitive material expiration label (Label # ABC).”
Documenting a Finding

• Things to do:
  – Put findings / corrections in order of Importance
  – Ensure wording is clear

• Things to avoid:
  – Emotional Words & Phrases
    • “extremely poor”, “nobody”, “perfect”, “I”, “I feel”, or “I think”
  – Bias & Slanted Viewpoints
    • “Not right because we do it differently at our plant…”
  – Nit-picking
    • “The word “Wire” was mis-spelled on the BOM…”
Audit Execution – Getting It Done

Communicating with the Auditee

- Provide audit status at least once a day
- Communicate any evidence that suggests an immediate and significant risk (e.g. safety, environment, quality) without delay
- Notify the auditee of findings as soon as possible
- Communicate with your team
Audit Execution – Getting It Done

Preparing the Audit Report

- Determine Audit Conclusions
- Determine Action Levels
  - Opportunity for Improvement
  - Correction
  - Corrective Action
- Prepare Draft Audit Report

Conduct Opening Meeting.
Conduct interviews and observations. Collect objective evidence.
Update Auditee periodically on issues found.
Prepare draft audit report and determine recommended action levels.
Review draft audit report with Auditee and assign responsibility.
Conduct Closing Meeting.
Determining Audit Conclusions

• Before preparing the audit report, audit team should:
  – Review the audit findings and any other information collected during audit against audit objectives
    • Look for systemic issues (Same types of observations in multiple areas / departments)
  – Agree on the audit conclusions, taking into account the uncertainty inherent with the audit process
  – Prepare recommendations, if specified by the audit objectives
Preparing Audit Conclusions

• Audit conclusions must address:
  – Is the process working effectively?
  – Extent of conformity of the quality management system to the criteria
  – The effective implementation, maintenance, and improvement of the quality management system
Audit report

- Audit Number
- Dates
- Processes Reviewed
- Audit Client
- Audit team leader and members
- Key contacts
- Audit summary (i.e., conclusions, findings, etc.)
- Corrective Action Tracking information
- Report Approvals

- If not an internal audit, may also want to include:
  - Products or Services Provided
  - Audit objective / purpose
  - Audit scope
  - Audit criteria
  - Information on any certifications
Audit Execution – Getting It Done

Review Audit Report with Auditee

- Review Audit Report with Auditee in detail.
- Obtain Auditee’s agreement and acceptance for identified findings.
- Obtain Corrective Action Request Numbers from Auditee for identified findings and agree on assignment of responsibility.

Conduct Opening Meeting.

Conduct interviews and observations. Collect objective evidence.

Update Auditee periodically on issues found.

Prepare draft audit report and determine recommended action levels.

Review draft audit report with Auditee and assign responsibility.

Conduct Closing Meeting.
Distribution of the report

- Upper Management (can vary)
- Auditee (Process Owner)
- Anyone who has responsibility for a Finding
- Audit team members
- As required, Official file copy
Audit Execution – Getting It Done

Conduct Closing Meeting

- Circulate Attendance Sheet
- Distribute copy of Audit Report to attendees.
- Revisit Audit Purpose / Scope
- Summarize Findings, Corrections, Opportunities for Improvements, and action follow-up results.
- Provide clarification as requested.
- Typically no more than 30 minutes.
Conducting the closing meeting

• Purpose of the closing meeting:
  – Present audit findings and conclusions in such a way that they are understood and acknowledged by the auditee.
  – Provide more details of findings, corrections, opportunities for improvements as requested by the auditee.
  – Where disputes arise or new information is made available by the auditee during the closing meeting, come to a consensus on changes to the Audit Report.
  – There should be **NO SURPRISES** on the Audit Report.
Audit Administration & Closure

Audit Planning, Preparation, & Notification → Audit Execution → Audit Administration & Closure → Action Implementation & Effectiveness Verification

- Collect working documentation and objective evidence from team members.
- Issue Final Audit Report and action requests.
- Forward documentation to Corrective Action Coordinator.

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Audit Administration & Closure

Collect Working Documentation

- Lead Auditor gathers working documentation and objective evidence from Team Members.
- Organize information and place in folder.
- Identify folder with Audit Number.
- Turn in to Quality or Audit Coordinator.

Issue Final Audit Report and action requests.

Forward documentation to Corrective Action Coordinator.
Audit Administration & Closure

Distribute Audit Report

- Internal Audits – Distributed by QA
  - Copy to:
    - Supervisor/Manager responsible for area audited
    - Auditors
    - Audit records file
    - Reviewed in Management Reviews

External Audit – Lead Auditor

- Auditee
- Facility Quality Manager
- Plant Manager
- Supplier Manager
- Quality Manager
- Supplier File

Collect working documentation and objective evidence from team members.

Issue Final Audit Report and action requests.

Forward documentation to Corrective Action Coordinator.
Audit Administration & Closure

**Distribute Corrective Action Requests**
- Original Provided to QA
- QA will determine assignments and issue
- Copy is included in Audit Folder

Collect working documentation and objective evidence from team members.

Issue Final Audit Report and action requests.

Forward documentation to Corrective Action Coordinator.
Audit Administration & Closure

Forward Documentation to QA

- Working Documentation
  - Audit Checklists
  - Auditor Notes
- Objective Evidence
- Opening / Closing Meeting Attendance Sheets
- Copy of Final Audit Plan, Audit Report
- Copies of Corrective Action Requests Issued

Collect working documentation and objective evidence from team members.

Issue Final Audit Report and action requests.

Forward documentation to Quality Assurance.
Audit Records

• Audit records are maintained for a minimum of three years after audit closure.

• Even after three years, request permission from Facility Quality Manager prior to disposal.

• Find out what your Organizations Record Requirements are.
Action Verifications – Post Audit

Audit Planning, Preparation, & Notification

Audit Execution

Audit Administration & Closure

Action Implementation & Effectiveness Verification

Review original action request and response.

Notify Auditee and make travel / logistics arrangements.

Request effectiveness data and compare to measures.

Review data and collect objective evidence to verify action(s) implementation and effectiveness.

Record results on CAR and review with Auditee.

Forward documentation to Corrective Action Coordinator.
Overview of Auditing Process

Audit Planning, Preparation, & Notification
- Prepare Audit Plan and Notify Auditee.
- Make travel / logistics arrangements.
- Review process documentation.
- Review results of previous audits.

Audit Execution
- Conduct Opening Meeting.
- Conduct interviews and observations. Collect objective evidence.
- Update Auditee periodically on issues found.
- Prepare draft audit report and determine recommended action levels.
- Review draft audit report with Auditee and assign responsibility.
- Conduct Closing Meeting.

Audit Administration & Closure
- Collect working documentation and objective evidence from team members.
- Issue Final Audit Report and action requests.
- Forward documentation to Corrective Action Coordinator.

Action Implementation & Effectiveness Verification
- Review original action request and response.
- Notify Auditee and make travel / logistics arrangements.
- Request effectiveness data and compare to measures.
- Review data and collect objective evidence to verify action(s) implementation and effectiveness.
- Record results on CAR and review with Auditee.
- Forward documentation to Corrective Action Coordinator.
QUESTIONS?

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Additional Information - Slides

- Resources used in development of material (1 slide)
- What is a Quality Management System (QMS)? (1)
- Roles /Responsibilities of Guides (1 slide)
- Objective Evidence (3 slides)
- Corrective Action Requests (2 slides)
Resources used in development of course material

• ISO 19011:2002: Guidelines for Quality and / or Environmental Management Systems Auditing
• ISO 9000:2008 Quality Management Systems - Fundamentals and Vocabulary
• ISO9000:2015 Quality Management Systems – Fundamentals and Vocabulary
• ISO 9001:2015 Quality Management Systems - Requirements
• ISO 9004:2008 Quality Management Systems - Guidelines for Performance Improvements
• How to Audit the Process-Based QMS: Dennis Arter, Charles A. Cianfrani, and John E. West
• Quality Audits for Improved Performance: Dennis Arter
• ASQ Quality Audits for Improved Performance Training Materials
What is a Quality Management System? (QMS)

Processes / procedures to ensure your products and services meet customer requirements.

- How proposals are processed
- How product or services are designed
- How Customer requirements are determined and met
- How products are produced
- How product quality is ensured
- How suppliers are qualified
- How progress on objectives is tracked and ensured
- How Employees are qualified
- How training is completed
- How service is provided
- How material is sourced
- How corrective action is taken and effectiveness ensured
- How performance is reviewed and actions assigned to improve
- How your QMS is verified as effective
Roles / Responsibilities of Guides

• Guides should assist the audit process by:
  – Establishing contacts and timing for interviews
  – Arranging visits to specific parts of the site or organization; providing guidance of the physical layout
  – Ensuring safety and security rules are known and followed by audit team members
  – Providing clarification or assisting in collecting information
  – Witnessing the process on behalf of auditee

• Guides should not be allowed to hinder the audit process by:
  – Leading the auditor to only those specific areas / individuals they want the auditor interview
  – Becoming involved in answering the interview question asked to the auditee
Objective Evidence

• Compare objective evidence to the audit criteria:
  – Objective evidence can;
    • Indicate compliance or noncompliance with the criteria
    • Identify opportunities for improvement
  • Objective evidence must be provided to support findings.
    – Findings should be reviewed with the auditee immediately.
Sources of Objective Evidence

- **Interviews** with Associates or other people
- **Observations** of activities and the surrounding work environment and conditions
- **Documents** (e.g. policy, objectives, plans, procedures, standards, instructions, licenses and permits, specifications, drawings, contracts, and orders)
- **Records** (e.g. inspection records, meeting minutes, audit reports, records of monitoring programs and results of measurements)
- **Data summaries, analyses and performance indicators**
- Information on the auditee’s sampling program and on procedures for the control of **sampling and measurement processes**
- **Reports** from other sources such as customer feedback or other relevant information from external parties and supplier ratings
- **Computerized databases and web sites**
Example of Objective Evidence

- Evidence of process performance through the end product (Comparing product with acceptance criteria)
- Evidence in product repeatability (How often it meets acceptance criteria and is it in line with process/system capability)
- Evidence in meeting quality objectives (Comparing what the goal was set at versus where the organization is now. Measurements that track progress).
- Identification of problems and how often they occur (correction, corrective action, preventive action)
- Evidence in getting better (process capability increases, reduction in rejects, exceeding set goals)
- Evidence of customer satisfaction improvement through measurable means
- Measurement and monitoring systems that show positive trends or action performed when data is not meeting expectations
- Evidence that customer, regulatory or standard requirements have been met (Comparison)
Corrective Action Requests

• The Auditor’s findings are the beginning event that triggers corrective action requests

• Communicate findings / corrections to those responsible for making changes (Usually this is a member of management)

• Internal auditors can suggest methods of corrective action
  – Depending on auditor’s involvement in system changes, he or she may need to disqualify themselves from verification of corrective action (loss of auditor’s independence)
Writing Corrective Action Requests

• Should be reported as it was communicated in the audit closing meeting and audit report
• Explain precisely what requirements were violated
• Comments must describe how audited activity failed to conform to the requirements (Avoid preaching)
• The nonconformity is to be written in such a manner that the problem found can be recreated by the assignee
• Includes all appropriate audit (objective) evidence